DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E-1221]

Determination of Regulatory Review Period for Purposes of Patent

Extension; Celexa

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined

the regulatory review period for Celexa and is publishing this

notice of that determination as required by law. FDA has made

the determination because of the submission of an application to

the Commissioner of Patents and Trademarks, Department of

Commerce, for the extension of a patent that claims that human

drug product.

ADDRESSES: Submit written comments and petitions to the Dockets

Management Branch (HFA-305), Food and Drug Administration, 5630

Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic

comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

     Claudia V. Grillo,

     Office of Regulatory Policy (HFD-007),

     Food and Drug Administration,

     5600 Fishers Lane,

     Rockville, MD 20857,

301-594-5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent
Term Restoration Act of 1984 (Public Law 98-417) and the Generic
Animal Drug and Patent Term Restoration Act (Public Law 100-670)
generally provide that a patent may be extended for a period of
up to 5 years so long as the patented item (human drug product,
animal drug product, medical device, food additive, or color
additive) was subject to regulatory review by FDA before the item
was marketed. Under these acts, a product's regulatory review
period forms the basis for determining the amount of extension an
applicant may receive.

A regulatory review period consists of two periods of time:
A testing phase and an approval phase. For human drug products,
the testing phase begins when the exemption to permit the
clinical investigations of the drug becomes effective and runs
until the approval phase begins. The approval phase starts with
the initial submission of an application to market the human drug
product and continues until FDA grants permission to market the
drug product. Although only a portion of a regulatory review
period may count toward the actual amount of extension that the
Commissioner of Patents and Trademarks may award (for example,
half the testing phase must be subtracted, as well as any time
that may have occurred before the patent was issued), FDA's
determination of the length of a regulatory review period for a

human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Celexa (citalopram hydrobromide). Celexa is indicated for the treatment of depression. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Celexa (U.S. Patent No. 4,650,884) from H. Lundbeck A/S, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 19, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Celexa represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Celexa is 5,498 days. Of this time, 5,061 days occurred during the testing phase of the regulatory review period, while 437 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective: July 30, 1983. The applicant claims August 4, 1983, as the date the investigational new drug application (IND)

became effective. However, FDA records indicate that the IND
effective date was July 30, 1983, which was 30 days after FDA
receipt of the IND.

2. <u>The date the application was initially submitted with
respect to the human drug product under section 505(b) of the
act</u>: May 7, 1997. FDA has verified the applicant's claim that
the new drug application (NDA) for Celexa (NDA 20-822) was
initially submitted on May 7, 1997.

3. <u>The date the application was approved</u>: July 17, 1998.
FDA has verified the applicant's claim that NDA 20-822 was
approved on July 17, 1998.

This determination of the regulatory review period
establishes the maximum potential length of a patent extension.
However, the U.S. Patent and Trademark Office applies several
statutory limitations in its calculations of the actual period
for patent extension. In its application for patent extension,
this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is
incorrect may submit to the Dockets Management Branch (address
above) written or electronic comments and ask for a
redetermination by [<u>insert date 60 days after date of publication
in the FEDERAL REGISTER</u>]. Furthermore, any interested person may
petition FDA for a determination regarding whether the applicant
for extension acted with due diligence during the regulatory
review period by [<u>insert date 180 days after date of publication</u>

in the FEDERAL REGISTER]. To meet its burden, the petition must
contain sufficient facts to merit an FDA investigation. (See H.
Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.)
Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets
Management Branch. Three copies of any information are to be
submitted, except that individuals may submit one copy. Comments
are to be identified with the

docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Dockets Management

Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: _____.

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Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research